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EXAMINER	
LLOYD, EMILY M	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,934	ROBERTS, PAUL R.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the RCE filed 29 September 2008. The Examiner acknowledges Applicant's amendments to claims 11 and 12 and the addition of claim 29. Currently, claims 11-19 and 21-29 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 11-19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 6931276 (Streng et al.) as modified by United States Patent 5662108 (Budd et al.).

Regarding claim 11, Streng et al. disclose an apparatus for detecting the location of electrical activity in the all of a human bladder, comprising: a detector (elongated threadlike electrode 10 Figure 1) adapted to be introduced into the bladder via the urethra (Column 3 lines 32-35), and having a connector to the exterior (wire 13 Figure 1 and Column 3 lines 41-16); and a filling lumen (channel of tube 20 Figure 1) adapted to permit passage of a sterile fluid from the exterior through an open end of the filling lumen into the bladder for distending the bladder (Column 3 lines 35-41). Streng et al. do not expressly disclose the use of an external closure for the filling lumen, the closure being effective when closed to maintain the bladder in a distended state, and being effective when released to drain the bladder. However, Budd et al. teach an inflation lumen (balloon catheter 94 Figure 3) having an external closure (Budd et al. the lumen inherently has a closure to keep the material inflating the balloon 96 Figure 3 inside of the balloon; it would have been obvious to have this closure externally for easy physician control to allow the balloon to deflate easily), the closure being effective when closed to maintain the balloon in an distended state (Figure 3), and being effective when released to drain the balloon (inherently the balloon is drained so that it can be removed from the body). It would have been obvious to one having ordinary skill in the art at the

time the invention was made to combine the external closure for a filling lumen as taught by Budd et al. with the invention of Streng et al. to provide for further testing of patients with urinary problems past the point of initially feeling the urge to void (the micturition reflex/detrusor reflex), as healthy people can wait until an appropriate time and location to void, and not voiding immediately would provide further data for comparing and diagnosing patients with urinary problems. Additionally, an external closure for the filling lumen would provide for not having urine and the testing fluid unexpectedly/prematurely leave the bladder.

Regarding claim 12, Streng et al. as modified by Budd et al. teach the apparatus according to claim 11, wherein the detector comprises an expandable device (Budd et al. inflatable balloon 96 Figure 3; basket catheter 80 Figure 4) adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder (Budd et al. Column 8 lines 64-67).

Regarding claim 13, Streng et al. as modified by Budd et al. teach the apparatus according to claim 12 wherein said expandable device has a plurality of detection sites thereon (Budd et al. “array or set of passive electrodes 48 typified by passive electrode 72” Column 5 lines 3-4 and Figure 3; “multiple passive electrode sites typified by electrode 84” Column 5 lines 23-24 and Figure 4).

Regarding claim 14, Streng et al. as modified by Budd et al. teach the apparatus according to claim 13 wherein said detection sites are uniformly distributed on the surface thereof (Budd et al. Figure 4).

Regarding claim 15, Streng et al. as modified by Budd et al. teach the apparatus according to claim 14. Streng et al. as modified by Budd et al. do not disclose expressly that the expandable device resembles a sphere in the expanded state. Instead, Streng et al. as modified by Budd et al. discloses the expandable device resembles an oblate shape (Budd et al. inflatable balloon 96 Figure 3).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the expandable device of Streng et al. as modified by Budd et al. into a spherical shape because Applicant has not disclosed that shaping the expandable device into a sphere provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Streng et al. as modified by Budd et al.'s expandable device, and Applicant's invention, to perform equally well with either the shape taught by Streng et al. as modified by Budd et al. or the claimed spherical shape because both shapes would perform the same function of providing a plurality of detection sites equally well considering the typical size of human anatomy.

Therefore, it would have been prima facie obvious to modify Streng et al. as modified by Budd et al. to obtain the invention as specified in claim 15 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Streng et al. as modified by Budd et al.

Regarding claim 16, Streng et al. as modified by Budd et al. teach the apparatus according to claim 14 wherein said expandable device comprises a cage (Budd et al. basket catheter 80 Figure 4) having a plurality of arcuate arms (Budd et al. limb 82

Figure 4) extending between opposite poles (Budd et al. proximal and distal ends of central shaft 86 Figure 4).

Regarding claim 17, Streng et al. as modified by Budd et al. teach the apparatus according to claim 12 and including an external telescopic connector whereby relative telescoping movement causes the device to expand and contract on demand (Budd et al. Column 8 lines 64-67; the device inherently can contract as it is also removable from the body).

Regarding claim 18, Streng et al. as modified by Budd et al. teach the apparatus according to claim 12 and comprising an inflatable device (Budd et al. inflatable balloon 96 Figure 3).

Regarding claim 19, Streng et al. as modified by Budd et al. teach the apparatus according to claim 18 wherein said device includes an inflation lumen (Streng et al. channel 22 Figure 3, Budd et al. balloon catheter 94 Figure 3) having an external closure (Budd et al. the lumen inherently has a closure to keep the material inflating the balloon 96 Figure 3 inside of the balloon; it would have been obvious to have this closure externally for easy physician control to allow the balloon to deflate easily).

Regarding claim 21, Streng et al. as modified by Budd et al. teach the apparatus according to claim 11 and comprising multiple lumens (Streng et al. parallel channels 22 and 24, Figures 3 and 4).

Regarding claim 22, Streng et al. as modified by Budd et al. teach the apparatus according to claim 11 and comprising an array of detection sites adapted to detect

electrical activity in the wall of the bladder whereby the location of said electrical activity can be determined (Budd et al. Column 9 lines 18-27).

Regarding claim 23, Streng et al. as modified by Budd et al. teach the apparatus according to claim 22 wherein said detection sites are uniformly distributed (Budd et al. Figure 4).

Regarding claim 24, Streng et al. as modified by Budd et al. teach the apparatus according to claim 12 and further comprising orientation means whereby the orientation of an expandable device in the bladder may be determined from outside the bladder (Budd et al. Column 11 line 44 – Column 12 line 7).

Regarding claim 25, Streng et al. as modified by Budd et al. teach the apparatus according to claim 12 and further including a lumen adapted to receive a stiff curved guide member for steering of the expandable device (Streng et al. channels 22 and 24 Figure 3; also Budd et al. a catheter such as balloon catheter 94 inherently has a lumen; any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art).

Regarding claim 26, Streng et al. as modified by Budd et al. teach the apparatus according to claim 11 and further including an ablation tool (Budd et al. therapy catheter 18 Figure 3) adapted for insertion through the urethra and operable to ablate (Budd et al. delivery electrode 60 Figure 3 and Column 5 lines 17-18) the internal surface of the bladder wall.

Regarding claim 27, Streng et al. as modified by Budd et al. teach the apparatus according to claim 26 wherein the tip of said tool (Budd et al. delivery electrode 60

Figure 16) is detectable by a position sensing apparatus (Budd et al. locator electrode 68 Figure 16).

Regarding claim 28, Streng et al. as modified by Budd et al. teach the apparatus according to claim 27 wherein the tip of said tool is adapted to be electrically active (Budd et al. delivery electrode 60 Figure 3) and wherein said apparatus is adapted to detect said activity (Budd et al. Column 4 lines 42-50).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Streng et al. as modified by Budd et al. as applied to claims 11-19 and 21-28 above, and further evidenced by Webster's II New Riverside University Dictionary.

Regarding claim 29, Streng et al. as modified by Budd et al. and as evidenced by Webster's II New Riverside University Dictionary teach the apparatus according to claim 11, wherein the external closure for the filling lumen comprises a valve (the external closure inherently comprises a valve, or "a device that regulates the flow of gases, liquids, or loose materials through a structure, as a pipe, or through an aperture by opening, closing, or obstructing a port or passageway" (Webster's II New Riverside University Dictionary pg 1275), as the fluid flow is stopped and started, or regulated, by the closure, and a valve performs this function).

Response to Arguments

7. Applicant's arguments filed 29 September 2008 have been fully considered but they are not persuasive.

Regarding Applicant's argument that it would not have been obvious to modify Streng et al.'s apparatus to have an external closure for the filling lumen as claimed, the

Examiner disagrees. While the invention of Streng et al. may be intended for use to stimulate the micturition reflex, it is well known in the art and in medicine that stimulation of the micturition reflex sends the message that the bladder is full. For healthy patients, this does not cause immediate voiding. However, in patients being tested, not allowing the bladder to drain immediately could provide additional information on the activity of the detrusor muscle and its relationship to bladder pressure, especially in comparison to that of a healthy individual who can voluntarily hold their urine after they have felt the micturition reflex.

Regarding Applicant's argument that Budd et al. does not disclose an external closure, the Examiner disagrees. The balloon in Figure 3 is clearly inflated with a fluid, and this fluid must have a closure in order to stay in the balloon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
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